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10/811,293

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Andy H. Levine

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/811,293

Applicant(s)

LEVINE ET AL.

Examiner

Cheryl Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 17, 18 and 20-50 is/are pending in the application.
- 4a) Of the above claim(s) 21-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17, 18, 20, 49, and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/13/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 13, 2007 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-20 and 49 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Kagan (US 2005/0240279 A1) does not disclose a restrictive member that is planar. The examiner disagrees. Kagan discloses two embodiments, one in figure 3 and the other in figure 11 that show a planar restrictive member. In figure 3, the top planar surface near the inlet aperture of stoma 100 is being considered the planar restrictive member. In figure 11, the planar screen of 202 is being considered the planar restrictive member that is *configured and capable* of placement in the stomach. The applicant has also argued that the restrictive member is not planar with a plane of the anchor. The examiner disagrees. The anchor is a three dimensional object and has many different planes. The restrictive member which is planar, is planar with one of the planes of the anchor. Further the term, "planar with a plane" is unclear, it seems the applicant may be intending to claim coplanar, however it is unclear as written.

The applicant has argued that Khosravi (US 5,925,063) does not disclose a single sheet membrane. The examiner disagrees. Membrane is considered to be 28+29 and is continuous along portion 29. Although there may be some slits, all portions are connected and thus may be considered a single sheet. Further, when in the implanted configuration, all members 28 align and touch, and thus form one layer and is a single sheet membrane. The applicant has also argued that the restrictive member is not removable. The examiner disagrees. The member is attached by an adhesive (or loops as taught by Saadat). Both adhesive and loops would permit the member to be removed. The member and anchor are two separate components that are attached, thus are *removable*. If a strong enough force is applied, that is for example a surgeon pulling the member off or tearing the member off the anchor, the member will remove, thus it is capable of being removed. The applicant has also argued that the member and anchor are not attached by a mechanical feature. The examiner disagrees. A mechanical feature may be considered the arced shaped the member and anchor form in the implanted configuration. The shapes are complimentary and thus meet up by a friction fit, the complimentary shapes considered the mechanical feature. If not the complimentary shape that is considered a mechanical feature, Saadat teaches alternate attachment means to the adhesive used by Khosravi. The applicant has additionally argued that Khosravi's clips (24) are not configured to penetrate tissue. The examiner disagrees. Clips 24 spring into place when snapping into apertures. Further the clips are shown to extend radially outward, thus would point into the adjacent tissue and be capable of penetrating it, see figure 6C wherein the clips are shown extending outward from the anchor.

The applicant has argued that Stack et al. (US 7,146,984 B2) does not disclose an implant that has an obvious size of 7-20cm. The examiner disagrees. Stack's implant is for placement in the stomach just as the applicant's device is. Although Stack's implant is placed at the proximal end of the stomach it still would be obvious to have different sizes to fit different patients. Different patients, for instance a child verses an adult will have different sized stomachs and stomach apertures. It would be obvious to size Stack's implant to fit the patient in need, and that patient would obvious have a sized in the range claimed, which is a very large size range claimed. The applicant has also argued that the member (42a) is not planar with a plane of the anchor. The examiner disagrees. The anchor is being considered (46a) or also the ring disclosed in col.5 line 60-col.6 line 3. This ring is coplanar with the member (42a).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 10, 12, 13, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kagan et al. (US 2005/0240279 A1, cited previously). See figures 3 and 11 and respective portions of the specification. Referring to claims 1, 3, 4, 49, and 50, Kagan discloses an implant (seen in fig.3 or 11) comprising a substantially planar restrictive member/means (top planar surface stoma 100 in fig.3 or planar member of 202 seen in fig.11), the restrictive member being a single sheet (top membrane of 100 in fig.3 and planar member of 202 in fig.11 appear to be a single membrane) and an anchor/anchor means (separate anchoring

ring structure 108 seen in fig.2a is disclosed to be used with all stoma embodiments; or outer ring of 202 seen in fig.11) removably coupled to the restrictive member (P0139, P0100; placed, replaced or exchanged) with a mechanical feature (disclosed sutures, clips; P0143), the restrictive member (top membrane of 100 in fig.3 or 202 in fig.11) being planar (see figs) with a plane of the anchor (the anchoring rings are three dimensional in shape and thus have many different planes; the restrictive member is inherently planar with one of those planes). Kagan discloses the implant for placement in the stomach substantially as claimed (fig.1, 2; P0002), however does not disclose the size (width) of the restrictive member and of the aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) and aperture size of (1-5 cm) since wherein the general conditions of a claim (membrane for use in the upper stomach) are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (size of membrane to fit the stomach) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Kagan discloses the restrictive member (100 or 202) to comprises a membrane having an aperture (110 in fig.3; see aperture of 202 in fig.11), the membrane being circular (fig.3, 11). Kagan discloses the anchor (ring of 202 in fig.11; or ring 108 seen in fig.2a) to comprise spring clips to anchor to the stomach (P0100, P0139, P0168).

Claims 1-10, 12-13, 17-18, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (US 5,925,063, cited previously). Referring to claims 1, 3, 4, 49, and 50, Khosravi discloses a gastrointestinal implant (fig.4B; col.6, lines 51-55) comprising a

substantially planar restrictive member (28+29, is substantially planar since the majority of the member is planar, portion 28), the member being a single sheet membrane (28+29 is one single sheet; although the sheet may have some slits in it, it is still continuous and connected through portion 29 and thus is a single sheet; further, when implanted, all flaps 28 touch and form one single layer membrane) having an interior aperture (33) and an anchor (stent 21) *configured* to couple to the stomach (col.6, lines 51-55) and removably couple to the restrictive member (is considered *removable*, may tear away adhesive) by a mechanical feature (complimentary shaped surfaces additionally provides a friction fit, the shaped surface considered the mechanical feature; in an alternative, it may be obvious to substitute the adhesive used by Khosravi with other attachment techniques such as sutures or clips as taught by Saadat below) the anchor (stent 21) having an exterior perimeter adapted to contact the stomach (fig.4B), the restrictive member substantially planar with a plane of the anchor (21; the anchor is three dimensional and have many different planes; the restrictive member is planar with one of the planes). Khosravi discloses the implant for placement in the stomach substantially as claimed (col.6, lines 51-55), however does not disclose the size (width) of the restrictive member and of the aperture. Khosravi discloses the implant for placement in the stomach substantially as claimed (any organ, gastrointestinal; col.6, lines 51-57), however does not disclose the size (width) of the restrictive member and of the aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) and aperture size of (1-5 cm) since wherein the general conditions of a claim (membrane for occluding or restricting for use in any organ-which includes the stomach, and for gastrointestinal use) are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (size of membrane to fit

the stomach) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to the remaining dependent claims, Khosravi discloses the restrictive member to be made of the materials claimed (col.4, lines 57-60; col.5, lines 1-5). Khosravi discloses the anchor (21) to have a plurality of clips (24, see fig.2, 6C) capable of penetrating tissue (shown to be angled radially outward in fig.6C, thus are capable of penetrating tissue). Khosravi discloses the anchor to be NiTi (col.4, lines 8-12).

In the alternative to the above rejection, claims 1-10, 12-13, 17-18, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (US 5,925,063, cited previously) in view of Saadat (US 7,160,312 B2, cited previously). Khosravi discloses a gastrointestinal implant (col.6, lines 51-55; fig.4B) substantially as claimed (see above). Khosravi discloses a restrictive member (28) coupled to an anchor (21), however uses adhesive (col.4, lines 36-39) instead of a mechanical hook and loop connection as claimed. Saadat teaches in the same field of gastrointestinal implants (abstract) the use of a hook and loop connection (205, see fig.21a, 21b) between a restrictive member (172) and anchor (176, 76) as an alternative to adhesive or other bondings (see figs.18, 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Khosravi's gastrointestinal implant having an attachment means (adhesive) with Saadat's teaching of an alternate attachment means for gastrointestinal implants, in order to provide an alternate attachment means to suit the needs of the patient (this one may be attached at the time of surgery).

Claims 1-13, 17-18, 20, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack et al. (US 7,146,984 B2, cited previously). Referring to claims 1, 3, 4, 49, and 50, Stack discloses a gastrointestinal implant (col.2, lines 21-23; fig.5B) comprising a substantially planar restrictive member (42a) that is a single sheet membrane (see fig.5B) having an interior aperture (44a) and an anchor (46a; or base ring disclosed at col.5 line 60-col.6 line 3) *configured* to couple to the stomach (col.2, lines 21-23) and removably couple to the restrictive member (is considered *removable*) by a mechanical feature (complimentary shapes forming a friction fit the anchor or disclosed sutures, clips, staples, col.6, lines 1-3), the member having an exterior perimeter adapted to contact the stomach, the member substantially planar (see fig.5b) with a plane of the anchor (see fig.5B). Stack discloses the implant for placement in the stomach substantially as claimed (col.2, lines 21-23), however does not disclose the size (width) of the restrictive member and of the aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) and aperture size of (1-5 cm) since wherein the general conditions of a claim (membrane for use in the stomach) are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (size of membrane to fit the stomach) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to the remaining dependent claims, Stack discloses the restrictive member (42a) to be made of the materials claimed (col.7, lines 15-18; col.4, lines 1-30). Stack discloses the restrictive member (42a) to have a feature (screws, snaps, sutures, clips, staples and other fasteners; col.5 lines 60-col.6 line 15) for coupling to the anchor (46a or 40a) and vice versa. Stack discloses the anchor (46a) to be NiTi (col.4, line 25).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/

  
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